FEB 16 2005

510(K) SUMMARY

510(k) Number: KO33696
Product: Personal Injector

Submitter's Name and Address:

Union Medico
Emdrupvej 22
2100 Copenhagen
Denmark

Contact Persons:

Michael Perthu
Jesper Hulbaek
Tel: +45 70266010
Fax: +45 70266011

Injector:

Personal Injector™

Class:

Class II

Classification Name:

Syringe Needle Introducers

Classification Panel:

General Hospital, Panel 80
Regulation Number 21 C.F.R § 880.6920

Predicate Device:

Autoject 2 (K993385)
Autoject 2 (K013362)

Manufacturing Facilities:

GPV Teknik A/S
Smedeland 22, Albertslund
2600 Glostrup
Denmark

Device Description

Personal Injector is designed for the user – by a user, and here for a lot of emphasis has been put on functionality and injection comfort, appearance, surface, materials, weight, balance, and sound. Personal Injector is an injection system allowing the user to have maximum control and comfort while injecting.

Personal Injector differs from commonly known Auto-injector. Until today, marketed Auto-injectors are only for subcutaneous injections, and introduce both the needle and the drug in one motion. The injections are associated with discomfort, such as pain, blue marks, drug accumulation and swelling at the injection site. Personal Injector has a spring-loaded mechanism that only serves to introduce the needle to a pre-determined depth, either subcutaneous or intramuscular. Hereafter the patient can check for air bobbles and vein penetration, and perform a safe traditional manual injection of the drug, by slowly and steady pushing the plunger down. Personal Injector minimises pain and support the patient perform the manual drug introduction, avoiding almost all discomfort.

Personal Injector two unique Syringe-Holders is designed to accommodate FDA approved syringes with fixed and non-fixed needles. Personal Injector is suitable for many injection regimes, including multiple sclerosis patients treatment with interferon beta, cancer treatment, children receiving growth hormone treatment, men injecting local vasodilators to treat erectile dysfunction, and injections of heparin, adrenaline, insulin, apomorphine, and many others medications.

Intended Use

The Device is intended to allow patients or carers to self-administer inject able FDA approved drugs or biologics with a safe, simple and easy injection system. Personal Injector is intended to be used in any setting including the home.

Operational

Personal Injector is designed to accommodate two different and replaceable syringe-holders. The injector is here for designed to use multiple FDA approved fixed or non-fixed needle syringes. Additionally, Personal Injector is intended for Prescription Use and Over-The-Counter Use.

Focus Group Study

Personal Injector has been tested at a focus group study in 2001 at Rigshospitalet, the largest MS hospital in Denmark, amongst patients using the Injector. The results were outstanding, and Personal Injector has received wide praise from Patients and Healthcare Professionals alike.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2005

Mr. Michael Perthu
Managing Director, CEO
Union Medico APS
Emdrupvej 22
2100 Copenhagen
DENMARK

Re: K033696
Trade/Device Name: Personal Injector
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: January 11, 2005
Received: January 13, 2005

Dear Mr. Perthu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

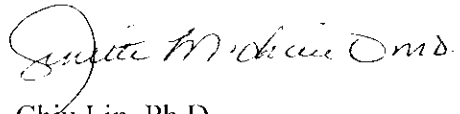
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K033696

Device Name: Personal Injector

Indications For Use:

Personal Injector is intended for use by patients to self-administer or by care-givers for injection of FDA approved drugs or biologics. Personal Injector is intended to introduce the needle below the skin surface.

Personal Injector is designed to accommodate two different and replaceable syringe-holders. Personal Injector is intended for the use with FDA approved fixed or non-fixed needle syringes supplied with specific injection regimens.

Personal Injector is intended to be used in any setting including the home.

Prescription Use ✓ AND/OR Over-The-Counter Use ✓

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K033696